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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,535	07/09/2001	Lorin Olson	LFS-132	7103

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EXAMINER
FONTAINE, MONICA A

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/901,535	Applicant(s) OLSON, LORIN	
	Examiner Monica A Fontaine	Art Unit 1732	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 33-52* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 34-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31,33 and 40-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This office action is in response to the Amendment filed 2 May 2003.

The following rejections have been withdrawn, as necessitated by amendment:

A. 35 USC 112 (2nd): Claims 30-32

B. 35 USC 103(a) over Lundin et al. (U.S. Patent 6,379,592), hereafter "Lundin," in view of Abrahamson (U.S. Patent 5,403,291): Claims 30, 31, and 33

C. 35 USC 103(a) over Lundin, in view of Abrahamson, in further view of Stiger (U.S. Patent 6,117,386): Claim 32

Election/Restrictions

This application contains claims 1-29 and 34-39 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 31, 33, 40, 41, 44, 45, 48, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Yeshurun (U.S. Patent 6,558,361).

Regarding Claim 30, Yeshurun shows that it is known in the prior art to carry out a method of manufacturing a micro-needle structure for penetrating the skin and other tissue barriers (Column 3, lines 10-13), said method comprising providing a suitable material from which said micro-needle structure can be fabricated by at least one micro-replication techniques (Column 3, lines 19-25), fabricating said micro-needle structure from said suitable material by said at least one micro-replication techniques (Column 3, lines 32-48), wherein said micro-needle structure comprises a proximal end defining a base having a center and a distal end having a vertex comprising a sharp tip (Column 3, lines 10-13), wherein said base has a diameter in the range of from about 100 to 2000μm (Column 11, lines 43-46) and a line extending from said center of the base to said vertex defines a structural axis having a length in the range from about 100 to 10000μm (Column 11, lines 43-47), and forming an open lumen within said micro-needle structure (Column 6, lines 60-61), said open lumen defining a lumenal axis and extending from said base to said vertex (Column 6, lines 60-61), wherein a distal end of said open lumen intersects said vertex (Figure 4) and wherein said lumenal axis and said structural axis are not co-axial (Column 7, lines 47-53).

Regarding Claim 31, Yeshurun shows the process as claimed as discussed above, including a method wherein said open lumen is formed during the step of fabricating (Column 7, lines 37-40).

Regarding Claim 33, Yeshurun shows the process as claimed as discussed above, including a method wherein said selectively angled tip comprises a beveled edge (Column 7, lines 58-60).

Regarding Claim 40, Yeshurun shows the process as claimed as discussed above, including a method further comprising forming a selectively angled tip at said vertex (Column 7, lines 3-4).

Regarding Claim 41, Yeshurun shows the process as claimed as discussed above, including a method wherein said suitable material is chosen from the group of a plastic and a resin (Column 8, lines 38-43).

Regarding Clain 44, Yeshurun shows the process as claimed as discussed above, including a method said suitable material comprises a metal (Column 3, lines 19-21).

Regarding Claim 45, Yeshurun shows the process as claimed as discussed above, including a method wherein the diameter of said open lumen is configured to exert a capillary force on a fluid present at said distal end of said open lumen (Column 11, lines 3-5).

Regarding Claim 48, Yeshurun shows that it is known in the prior art to carry out a method of manufacturing a micro-needle structure for penetrating the skin and other tissue barriers (Column 3, lines 10-13), said method comprising providing a suitable material from which said micro-needle structure can be fabricated by at least one micro-replication techniques (Column 3, lines 19-25), fabricating said micro-needle structure from said suitable material by said at least one micro-replication techniques (Column 2, lines 40-43; Column 3, lines 32-48), wherein said micro-needle structure comprises an oblique cone configuration having a base and a vertex configured for penetrating the skin and other tissue barriers (Column 2, lines 40-43;

Column 3, lines 5-7), forming an open lumen within said micro-needle structure (Column 6, lines 60-61), said open lumen defining a lumenal axis and extending from said base to said vertex (Column 6, lines 60-61); and integrating said micro-needle structure with another structure wherein said open lumen is in fluid communication with said other structure (Column 6, lines 51-64; element 12: "another structure", element 16: "micro-needle").

Regarding Claim 52, Yeshurun shows the process as claimed as discussed above, including a method further comprising fabricating a plurality of micro-needle structures and integrating said plurality with said other structure wherein said open lumen of each said micro-needle structure is in fluid communication with said other structure (Column 6, lines 51-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42, 43, 46, 47, 49, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeshurun, in view of Massau (U.S. Patent 4,838,877).

Regarding Claim 42, Yeshurun shows the process as claimed as discussed above, but does not show forming a micro-needle with a specific material. Massau shows that it is known to carry out a method for making a micro-needle, wherein a suitable material is polycarbonate (Column 6, lines 31-40). Massau and Yeshurun are combinable because they are concerned with a similar technical field, namely, that of making needles whose aim is to minimize pain felt by a

patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polycarbonate as the suitable material when making Yeshurun's micro-needle in order to use a material that is compatible with living tissue.

Regarding Claim 43, Yeshurun shows the process as claimed as discussed above, but does not show injection molding. Massau shows that it is known to make a needle wherein said at least one replication technique comprises injection molding (Column 6, lines 50-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Massau's injection molding to make Yeshuru's micro-needles in order to use current injection molding technology.

Regarding Claim 46, Yeshurun shows that it is known to carry out a method of manufacturing a micro-needle structure (Column 3, lines 10-13), said method comprising providing a plastic material (Column 2, lines 40-43; Column 3, lines 32-48), fabricating said micro-needle structure with said plastic material (Column 2, lines 40-43; Column 3, lines 32-48), wherein said micro-needle structure comprises an oblique cone configuration having a base and a vertex comprising a sharp tip (Column 2, lines 40-43; Column 3, lines 5-7), and forming an open lumen within said micro-needle structure, said open lumen extending from said base to said vertex wherein a distal end of said open lumen intersects said vertex (Column 6, lines 60-61; Figure 4). Yeshurun does not show forming a micro-needle with injection molding. Massau shows that it is known to make a needle wherein said at least one replication technique comprises injection molding (Column 6, lines 50-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Massau's injection molding to make Yeshuru's micro-needles in order to use current injection molding technology.

Regarding Claim 47, Yeshurun shows the process as claimed as discussed above, including a method wherein a line extending from a center of said base to said vertex defines a structural axis, wherein said open lumen defines a lumenal axis, and wherein said lumenal axis and said structural axis are not co-axial (Column 7, lines 47-53), meeting applicant's claim.

Regarding Claims 49 and 50, Yeshurun shows the process as claimed as discussed above, but does not show a means for receiving fluid. Massau shows that it is known to make a needle connected to another structure, wherein said other structure is provided with means (Claim 49) for receiving and measuring a constituent of fluid received therein, and (Claim 50) holding an amount of fluid therein (Column 5, lines 32-40; It is noted that if fluid being *held* in a chamber, at some previous time, a sufficient or *"measured"* amount of fluid was *received* in some fashion into the chamber.). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form Massau's fluid-receiving chamber in Yeshurun's molded micro-needle in order to enable more fluid to be stored in the needle, eliminating the need for superfluous containers.

Regarding Claim 51, Yeshurun shows the process as claimed as discussed above, but does not show a specific type of fluid. Massau shows that it is known to have a therapeutic agent as the fluid in his molded needle (Column 1, lines 8-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Massau's therapeutic fluid in Yeshurun's molded micro-needle in order to administer healing fluid to the patient.

Response to Arguments

Applicant's arguments with respect to claims 30-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following article is cited to further show the state of the art with regard to microneedles and the manufacture thereof:

Stoeber, Boris and Dorian Liepmann. "Two-Dimensional Arrays of Out-of-Plane Needles". Berkeley Sensor and Actuator Center, University of California at Berkeley. Given as a presentation June 4-8, 2000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 703-305-7239. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill L. Heitbrink can be reached on 703-308-0673. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9310 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

maf
June 24, 2003

JILL L. HEITBRINK
PRIMARY EXAMINER
ART UNIT ~~137~~ 1732
6/25/03